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William J. McNichol, Jr., Esquire Reed Smith LLP 2500 One Liberty Place 1650 Market Street Philadelphia, PA 19103-7301		EXAMINER GHALI, ISIS A D		
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DATE MAILED: 10/25/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/613,698

Applicant(s)

PATEL ET AL.

Examiner

Isis Ghali

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/04/2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 21-35 is/are pending in the application.
- 4a) Of the above claim(s) 19, 21-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 34 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The receipt is acknowledged of applicants' amendment filed 10/04/2006.

Claim 20 has been canceled

Claims 34 and 35 have been added.

Claims 1-19, 21-35 are pending.

Response to Election/Restrictions

1. Applicant's election with traverse of 1-18 during telephone conversation on June 14, 2006 is acknowledged. The traversal is on the ground(s) that both groups have the same classification and require the same field of search. This is not found persuasive because the two inventions can stand two separate patents in the art because the system of claim 1 has different composition from the system of claim 19. Invention I requires water insoluble active ingredient in an emulsion while invention II does not require an emulsion and requires one specific active agent, and on the other hand invention I does not require all the ingredients required by invention II. Additionally the different inventions will have different functions as implied by the different compositions. The prior art that anticipates invention I may not anticipates invention II.

The requirement is still deemed proper and is therefore made FINAL.

2. This application contains claims 19, 21-33 drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-18 and 34-35 are included in the prosecution.

The rejection of claims 3 and 4 as failing to comply with the written description requirement has been withdrawn by virtue of applicants' remarks.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 2, 5-18, 34-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection. To satisfy the Written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that applicant were in

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possession of the claimed invention. Applicant's claims are drawn to insoluble active ingredient in an emulsion. The specification on paragraph 12, applicants disclose "insoluble drug including but not limited to prodrugs, herbal medicines, traditional medicines, and active cosmetic ingredients". There is no definition given to these medicines and active ingredients. The specification gives no guidance to one of ordinary skill in the art to the insoluble active ingredients. The specification defines one insoluble drug: benzoyl peroxide (BPO). The expression "insoluble drug in emulsion" does not convey to one of ordinary skill in the art that applicants were in possession of the claimed subject matter. Claims employing language at the point of novelty, such as applicants' "insoluble drugs in an emulsion", neither provide those elements required to practice the inventions, nor "inform the public" during the life of the patent of the limits of the monopoly asserted. The insoluble drug could encompass myriad of insoluble drugs and applicants claimed "insoluble drugs in an emulsion" represents only an invitation to experiment regarding possible drugs.

Response to Arguments

5. Applicant's arguments filed 10/04/2006 have been fully considered but they are not persuasive. Applicants traverse the written description rejection by arguing that "traditional medicine", "herbal medicine", prodrugs" and "insoluble active ingredients" are art recognized.

In response to this argument, it is well established that to satisfy the Written description requirement, applicant must convey with reasonable clarity to one skilled in

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the art, as of the filing date that applicant were in possession of the claimed invention, and not what recognized by the art. The specification lack description to traditional and herbal medicine, prodrugs and cutaneously active cosmetics that makes applicants in possession of the claimed invention with regard to what are these terms and which medicine, prodrug, or active agent is soluble in which solvent. The expressions "traditional medicine", "herbal medicine", "prodrug", "cutaneously active cosmetic" and "insoluble dermatologically active agents" without i.e. partial or complete description does not convey to one of ordinary skill in the art that applicants were in possession of the claimed subject matter. The functional language recited without any correlation does not meet the written description requirement for the claimed expressions as one of ordinary skill in the art could not recognize or understand the drug or medicine from the mere recitation of the function and correlate which medicine or drug is soluble in which solvent.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 6, 7, 14-18 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,562,642 ('642).

US '642 discloses a non-woven pad impregnated by dermatologically active ingredients wherein the non-woven material is capable of absorbing a flowable liquid composition of the active ingredients (abstract; col.4, lines 37-39; col.5, lines 25-31; col.8, lines 21-34). The active ingredients include benzoyl peroxide, which is inherently insoluble, and antibiotic including neomycin, clindamycin, erythromycin, or cortisone which read on claim 17-18 (col.10, lines 46-52). The composition is an emulsion (col.14, lines 38-40; table VI; col.20, lines 15-35). The pad is contained in a container comprising aluminum foil layer in contact or sealed with thermoplastic layer that is sealable by heat, which packaging is not prone to premature rupture but provides ready dispensing of the package contents (col.3, lines 55-57; col.8, lines 45-59). The pad can be impregnated by antifungal agent or other dermatologically active agents (col.11, lines 50-52). Viscosity is inherent to a specific composition.

Response to Arguments

8. Applicant's arguments filed 10/04/2006 have been fully considered but they are not persuasive. Applicants argue that US '642 does not anticipate the claims because it does not teach the claimed viscosity, and viscosity is not inherent. Viscosity and particle sizes prevent the liquid from draining out from the pad.

In response to this argument against the anticipatory rejection over US '642, it is argued that claim 1 does not recite any active agent or any ingredient of the emulsion, therefore, the US '642 anticipates claim 1, and the viscosity is an inherent for the specific composition. US '642 recognized the desire to increase the viscosity of the

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composition to allow retention of the composition into the substrate, as applicants have done. Since the essential elements of the '642 composition are identical to the instant compositions, i.e. composition comprising insoluble active agent and emulsion, the '642 composition is expected to have the same physiochemical properties as the composition set forth in the instant application, such as viscosity of the composition, depending on which insoluble drug and which emulsion are used. As such, it is the examiner's position that the composition advanced by '642 anticipates the compositions enumerated in the instant claim set. It has been held that the failure of those skilled in the art to contemporaneously recognize an inherent property, function, or ingredient of a prior art reference does not preclude a finding of anticipation. Whether or not an element is inherent in the prior art is a fact question. Inherency is not necessarily conterminous with knowledge of those of ordinary skill in the art, who may not recognize the inherent characteristics or functioning of the prior art. However the discovery of a previously unappreciated property of a prior art composition does not render the old composition new to the discoverer. See *Atlas Powder versus Ireco*, 51 USPQ 2d 1943, (Fed. Cir. 1999).

9. Claims 1, 2, 6, 7, 14, 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,183,766 ('766).

US '766 discloses non-woven pad impregnated by composition in the form of emulsion comprising: benzoyl peroxide (col.12, line 56); glycerin (col.11, line 42); antifungal agent (col.12, line 64); and glycerin, perfumes, erythromycin, which reads on

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claims 17-18 (col.11, lines 47; col.12 lines 17, 58-59; col.13, lines 44-45). The pads are contained in a container (col.17, lines 41-45). The preferred droplet size of the emulsion is from 0.2 to 200 microns (col.4, lines 24-28). Viscosity is inherent to a specific composition.

Response to Arguments

10. Applicant's arguments filed 10/04/2006 have been fully considered but they are not persuasive. Applicants argue that US '766 failed to teach the claimed viscosity, and teaches viscosity with respect to specific ingredient and not the viscosity of the final composition. The reference does not teach the claimed particle sizes.

In response to this argument against the anticipatory rejection over US '766, it is argued that claim 1 does not recite any active agent or any ingredient of the emulsion, therefore, the US '766 anticipates claim 1, and the viscosity is an inherent for the specific composition. Since the essential elements of the '766 composition are identical to the instant compositions, i.e. composition comprising insoluble active agent and emulsion, the '766 composition is expected to have the same physiochemical properties as the composition set forth in the instant application, such as viscosity of the composition, depending on which insoluble drug and which emulsion are used. As such, it is the examiner's position that the composition advanced by '766 anticipates the compositions enumerated in the instant claim set. It is also noticed that the claims that recite the particle sizes are not included in the anticipatory rejection over US '766. It has been held that the failure of those skilled in the art to contemporaneously recognize an

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inherent property, function, or ingredient of a prior art reference does not preclude a finding of anticipation. Whether or not an element is inherent in the prior art is a fact question. Inherency is not necessarily conterminous with knowledge of those of ordinary skill in the art, who may not recognize the inherent characteristics or functioning of the prior art. However the discovery of a previously unappreciated property of a prior art composition does not render the old composition new to the discoverer. See *Atlas Powder versus Ireco*, 51 USPQ 2d 1943, (Fed. Cir. 1999).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 3-5, 8-13, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '642.

The teachings of US '642 are discussed above. US '642 does not teach the BPO in an emulsion, the claimed particle size and viscosity, or the woven material.

US '642 suggests the use of BPO for skin application from a pad and also suggests the emulsion. Therefore, one having ordinary skill in the art at the time of the invention would have been motivated to include BPO in the emulsion of table VI, motivated by the skill of versed artisan that BPO is effective to treat acne, with reasonable expectation of having emulsion comprising BPO impregnated into a pad wherein the emulsion is delivered cutaneously and effective against acne.

The claimed particle sizes and viscosities do not impart patentability to the claims, absent evidence to the contrary. It is expected that the viscosity of the composition disclosed by the reference having the same ingredients as the claimed composition to have the same viscosity. The art suggests the low viscosity of the liquid composition as implied by the flowability of the composition in order to be absorbed into the non-woven pad.

The woven material does not impart patentability to the claims, absent evidence to the contrary.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the non-woven pad impregnated with composition comprising benzoyl peroxide in an emulsion in a container as disclosed by the

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reference, and adjust the viscosity motivated by the desire of the reference to obtain flowability of the composition suitable for the composition to be absorbed into the pad, as also desired by applicants, with reasonable expectation of having pad that deliver active benzoyl peroxide when wiped to the skin.

14. Claims 3-5, 8-13, 34 and 35 rejected under 35 U.S.C. 103(a) as being unpatentable over US '766.

The teachings of US '766 are discussed above. US '766 does not teach the BPO in an emulsion, the claimed viscosity, or the woven material.

US '766 suggests the use of BPO for skin application from a pad and also suggests the emulsion. Therefore, one having ordinary skill in the art at the time of the invention to include BPO in the emulsion, motivated by the skill of versed artisan that BPO is effective antimicrobial agent and effective to treat acne, with reasonable expectation of having emulsion comprising BPO impregnated into a pad wherein the emulsion is effective against bacteria and acne.

The claimed viscosities do not impart patentability to the claims, absent evidence to the contrary. It is expected that the viscosity of the composition disclosed by the reference having the same ingredients as the claimed composition to have the same viscosity. The art suggests adding viscosity enhancer to the composition impregnated into pad.

The woven material does not impart patentability to the claims, absent evidence to the contrary.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the non-woven pad impregnated with composition comprising benzoyl peroxide in an emulsion in a container as disclosed by the reference, and adjust the viscosity motivated by the desire of the reference to obtain viscous fluid to be absorbed into the pad, as also desired by applicants, with reasonable expectation of having pad that deliver active benzoyl peroxide when wiped to the skin.

Response to Arguments

15. Applicant's arguments filed 10/04/2006 have been fully considered but they are not persuasive. The main gist of applicants' argument against the rejection of claims 3-5 and 8-13 over any of US '642 and US '766 is that both references do not teach the viscosity and the particle sizes of the active ingredients.

In response to this argument, it is noted that viscosity of a chemical compounds is a property that cannot be separated from the compounds and compositions having the same ingredients are expected to have the same viscosity. Both of US '642 and US '766 teach pad impregnated by emulsion comprising active agents, and this implies that the emulsion is retained in the pad. None of the references teach the emulsion is present separate from the pad in the container. If the emulsion composition of the prior art made from the same materials as the composition of the present claims, then it is expected that the composition of the prior art will have the same viscosity as the instantly claimed composition. The rejected claim do not recite any specific materials for the emulsion composition that are responsible for the viscosity. The particles size of the

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active agent is the only difference between the cited references and the present claims, and it would have been obvious to one having ordinary skill in the art at the time the invention was made to select the particle sizes, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable / ranges involves only routine skill in the art. *In re Aller* 105 USPQ 233.

16. Claims 4, 5, 34, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '624 in view of US '766.

The teachings of the references are discussed above, however, US '642 does not teach the particle size as claimed in claims 4 and 5.

US '766 teaches particles sizes of the emulsion are preferred to be between 0.2 and 200 micron.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the emulsion disclosed by US '642 with particle sizes between 0.2 and 200 micron motivated by the teaching of US '766 that this range of droplet size is preferred for emulsion impregnated in a pad to deliver active agents to the skin, with reasonable expectation of having emulsion having droplet sizes of 0.2 and 200 micron impregnated in a pad that deliver active ingredients to the skin with great success.

Response to Arguments

17. Applicant's arguments filed 10/04/2006 have been fully considered but they are not persuasive. Applicants traverse the above rejection by arguing that US '766 does not teach the particle sizes of BPO.

In response to this argument, it is argued that the particles size of the active agent is the only difference between the cited references and the present claims, and it would have been obvious to one having ordinary skill in the art at the time the invention was made to select the particle sizes, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable / ranges involves only routine skill in the art. *In re Aller* 105 USPQ 233.

18. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over US '766 in view of US '642.

The teachings of the references are discussed above, however, US '766 does not teach the package as claimed in claim 15.

US '642 teaches package as claimed in claim 15 as not prone to premature rupture but provides ready dispensing of the package contents.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide pad impregnated with active agent in an emulsion and contained in a container as disclosed by US '766, and replace the container by the container disclosed by US '642 that comprises aluminum foil layer in contact or sealed with thermoplastic layer, motivated by the teaching of US '642 that this package is not prone to premature rupture but provides ready dispensing of the package contents, with

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reasonable expectation of having pad containing active agent in an emulsion and packaged in package comprises aluminum foil layer in contact or sealed with thermoplastic layer that is not prone to premature rupture but provides ready dispensing of the package contents.

Response to Arguments

19. Applicant's arguments filed 10/04/2006 have been fully considered but they are not persuasive. Applicants argue that US '642 and US '766 failed to teach the claimed viscosity and if combined, they fail to teach every element of the claimed invention.

In response, it is argued that US '766 is combined with US '642 to reject claim 15 that is directed to specific materials of the container that is not disclosed by US '766 but disclosed by US '642. The viscosity is property of materials and it is inherent in the teachings of US '642 and US 766, and applicants do not claim any specific material for the emulsion composition.

20. Claims 1-18, 34, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,784,145 in view of US '642.

US '145 teaches nonwoven substrate impregnated with composition in the form of an emulsion comprising active agent such BPO, insoluble, erythromycin, soluble, neomycin, antifungal (abstract; col.6, lines 37-38, 45; col.7, lines 7, 14-15). The emulsion is either water/oil or oil/water emulsion (col.3, lines 35-44). The composition has viscosity preferably below 150 mPa.s in order to be suitable to impregnate the

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substrate (col.3, lines 24-28). The mean size of the globules of the emulsion is between 50-1000 microns in order to be suitable to impregnate the substrate (col.7, lines 63-67).

However, US '145 does not teach the impregnated substrate is contained in a container.

It is implied by the teaching of the reference that wipes and substrates impregnated with liquid composition are packaged in containers.

US '642 teaches a container for substrate impregnated with a liquid composition, as discussed above.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an article comprising nonwoven substrate impregnated with active agent in an emulsion as disclosed by US '145, and package the article in the container disclosed by US '642 that comprises aluminum foil layer in contact or sealed with thermoplastic layer, motivated by the teaching of US '642 that this package is not prone to premature rupture but provides ready dispensing of the package contents, with reasonable expectation of having substrate impregnated with active agent in an emulsion and packaged in package comprises aluminum foil layer in contact or sealed with thermoplastic layer that is not prone to premature rupture but provides ready dispensing of the package contents.

21. Claims 4, 5, 8-12, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '642 in view of US '145.

The teachings of the references are discussed above.

US '642 does not teach the particle sizes and viscosity of the emulsion, which is taught by US '145.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an article comprising nonwoven substrate impregnated with active agent in an emulsion and contained in a container as disclosed by US '642, and adjust the droplet sizes of the emulsion between 50-1000 microns and the viscosity to below 150 mPa.s as disclosed by US '145, motivated by the teaching of US '145 that these parameters are suitable to allow the emulsion to impregnate the substrate, with reasonable expectation of having a packaged article comprising substrate impregnated with emulsion having particle sizes of 50-1000 micron and viscosity less than 150 mPa.s wherein the composition impregnates the substrate and retained in there successfully till time of use.

Response to Arguments

22. Applicant's arguments filed 10/04/2006 have been fully considered but they are not persuasive. Applicants traverse the rejections over US '642 combined with US '145 by arguing that US '145 teaches viscosity below the claimed viscosity, and failed to teach the particle sizes.

In response to this argument, it is argued that US '145 teaches emulsion composition comprises BPO as instantly claimed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to select the particle sizes and viscosity, since it has been held that where the general conditions of a claim

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are disclosed in the prior art, discovering the optimum or workable / ranges involves only routine skill in the art. *In re Aller* 105 USPQ 233.

23. Claims 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '766 in view of US '145.

The teachings of the references are discussed above.

US '766 does not teach the viscosity of the emulsion, which is taught by US '145.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an article comprising nonwoven substrate impregnated with active agent in an emulsion and contained in a container as disclosed by US '766, and adjust the viscosity of the emulsion to below 150 mPa.s as disclosed by US '145, motivated by the teaching of US '145 that this viscosity is suitable to allow the emulsion to impregnate the substrate, with reasonable expectation of having a packaged article comprising substrate impregnated with emulsion having viscosity less than 150 mPa.s wherein the composition impregnates the substrate and retained in there successfully till time of use.

Response to Arguments

24. Applicant's arguments filed 10/04/2006 have been fully considered but they are not persuasive. Applicants traverse the above rejections by arguing that US '766 and US '145 do not teaches the claimed viscosity, and failed to teach the particle sizes.

In response to this argument, it is argued that US '145 teaches emulsion composition comprises BPO as instantly claimed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to select the particle sizes and viscosity, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable / ranges involves only routine skill in the art. *In re Aller* 105 USPQ 233.

25. Claims 1-18, 34, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,338,855 ('855) in view of US '642.

US '855 teaches article for delivering active agents to the skin comprises woven or nonwoven substrate impregnated with composition in the form of emulsion comprising BPO as preferred active agent, antifungal, water soluble agents (abstract; col.6, lines 13-17; col.17, lines 30-31, 42, 55-57; col.18, lines 18, 30-40; col.25, lines 66-67; col.26, lines 19-26; col.55, lines 37-67). The composition further comprises material to adjust the viscosity the composition remains on the substrate (col.49, lines 35-50).

US '855 does not teach the article in a container, or particle sizes or the viscosity of the composition.

It is implied by the teaching of the reference that wipes and substrates impregnated with liquid composition are packaged in containers.

US '642 teaches a container for substrate impregnated with a liquid composition, as discussed above.

The claimed particle sizes and viscosity do not impart patentability to the claims because the art recognized the desire to have viscosity of the impregnated composition enough to retain the composition in the pad, absent evidence to the contrary.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an article comprising nonwoven substrate impregnated with active agent in an emulsion as disclosed by US '855, and package the article in the container disclosed by US '642 that comprises aluminum foil layer in contact or sealed with thermoplastic layer, motivated by the teaching of US '642 that this package is not prone to premature rupture but provides ready dispensing of the package contents, with reasonable expectation of having substrate impregnated with active agent in an emulsion and packaged in package comprises aluminum foil layer in contact or sealed with thermoplastic layer that is not prone to premature rupture but provides ready dispensing of the package contents.

Response to Arguments

26. Applicant's arguments filed 10/04/2006 have been fully considered but they are not persuasive. Applicants argue that US '855 teaches dry pad that is wetted before use while the present invention is composition retained in the pad. US '855 and US '642 do not teach the particle sizes and viscosity as claimed.

In response to this argument, it is argued that the present claims are directed to an article comprising pad and composition impregnated into the pad, and all the elements of the article are disclosed by the reference. US '855 teaches nonwoven

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substrate impregnated with composition in the form of emulsion comprising BPO, as instantly claimed. Wetting of the pad of the prior art before use does not constitute a teaching away from the present claims because the product of the prior art makes the present claims obvious. US '642 in this rejection is relied upon for its solely teaching of the container. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an article comprising nonwoven substrate impregnated with active agent in an emulsion as disclosed by US '855, and package the article in the container disclosed by US '642 that comprises aluminum foil layer in contact or sealed with thermoplastic layer, motivated by the teaching of US '642 that this package is not prone to premature rupture but provides ready dispensing of the package contents, with reasonable expectation of having substrate impregnated with active agent in an emulsion and packaged in package comprises aluminum foil layer in contact or sealed with thermoplastic layer that is not prone to premature rupture but provides ready dispensing of the package contents. Regarding the viscosity and the particle sizes, it would have been obvious to one having ordinary skill in the art at the time the invention was made to select the particle sizes and viscosity, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable / ranges involves only routine skill in the art. *In re Aller* 105 USPQ 233.

27. Claims 4, 5, 8-12, 34, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '855 in view of US '642 and further in view of US '145.

Although the cited references recognized the importance of changing the viscosity of the composition to allow the composition to remain on the substrate, the combined teaching of US '855 and US '642 does not teach the exact particle sizes and viscosities as claimed by applicants.

US '145 teaches the same ranges of particle sizes and viscosity of the composition because and teaches that these parameters are suitable for impregnating the composition into a substrate.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an article comprising woven or nonwoven substrate impregnated with active agent in an emulsion and contained in a container as disclosed by the combined teachings of US '855 and 642, and adjust the droplet sizes of the emulsion between 50-1000 microns and the viscosity to below 150 mPa.s as disclosed by US '145, motivated by the teaching of US '145 that these parameters are suitable to allow the emulsion to impregnate the substrate, with reasonable expectation of having a packaged article comprising substrate impregnated with emulsion having particle sizes of 50-1000 micron and viscosity less than 150 mPa.s wherein the composition impregnates the substrate and retained in there successfully till time of use.

Response to Arguments

28. Applicant's arguments filed 10/04/2006 have been fully considered but they are not persuasive. Applicants argue that the prior art does not teach the claimed viscosity

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and particle sizes, and one of ordinary skill in the art would not be motivated to combine the references.

Regarding the viscosity and the particle sizes, it would have been obvious to one having ordinary skill in the art at the time the invention was made to select the particle sizes and viscosity, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable / ranges involves only routine skill in the art. *In re Aller* 105 USPQ 233. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, in this case one having ordinary skill in the art at the time of the invention would have provided pad impregnated with emulsion and BPO in a container as disclosed by the combined teaching of the references, and adjust the viscosity and particle sizes of the active agents according to the intended use of the article.

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are

evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been prima facie obvious within the meaning of 35 U.S.C. 103 (a).

Conclusion

29. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

IG

Isis Ghali
TC 1600